DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 4, 2002, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, the Ballroom, Two Montgomery Village Ave., Gaithersburg, MD, 301–948–8900.

Contact Person: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider supplemental new drug application S–047, Clozaril, (clozapine, Novartis Pharmaceuticals Corp.) proposed for the treatment of suicidality in patients with schizophrenia or schizoaffective disorder. The purpose of this meeting is to discuss the findings and regulatory implications for the InterSePT Study, a study that compared clozapine and olanzapine on the outcome of emergent suicidal behavior and thinking in schizophrenic and schizoaffective patients who were judged to be at risk of suicide. Background material for this meeting will be posted no later than 24 hours before the meeting at the Psychopharmacologic Drugs Advisory Committee Docket site: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2002 and scroll down to Psychopharmacologic Drugs Advisory Committee.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 24, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 24, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until December 17, 2002, the comment period for the draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' This draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples. FDA published a notice of availability of the draft guidance in the **Federal Register** of August 21, 2002 (67 FR 54219). The agency is taking this action in response to a request for an extension of the comment period and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidance by December 17, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed, adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 21, 2002 (67 FR 54219), FDA announced the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' The draft guidance had a 30-day comment period. The draft guidance clarifies the responsibilities of the involved parties for retention of samples used in bioavailability and bioequivalence studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

In a letter dated September 20, 2002, FDA received a request from an interested party to extend the comment period. The party indicated that issues of importance to the pharmaceutical industry had been raised that warrant further discussion before filing comments. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period for 60 days.